

**NOT FOR PUBLICATION**

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

**AMGEN INC., *et al.*,**

**Plaintiffs,**

**v.**

**KASHIV BIOSCIENCES, LLC, *et al.*,**

**Defendants.**

**Civil Action No. 18-3347 (CCC)**

**OPINION**

**FALK, U.S.M.J.**

Before the Court is the motion of Plaintiffs, Amgen Inc. and Amgen Manufacturing Limited (together herein, “Amgen”), for leave to amend their infringement contentions. [ECF No. 141.] Defendants Kashiv Biosciences, LLC; Amneal Pharmaceuticals, LLC; and Amneal Pharmaceuticals, Inc. (collectively, “Defendants”) oppose the application, in part. No oral argument is necessary. For the reasons stated below, the motion is **GRANTED**.

**RELEVANT BACKGROUND**

This is a patent infringement suit involving three patents covering Amgen’s filgrastim-based biological drug product, referred to by the brand name Neupogen®. The suit is brought pursuant to the Biologics Price Competition and Innovation Act of

2009 (“BCPIA”). Defendants seek approval to license a “biosimilar” of Amgen’s product pursuant to an abbreviated regulatory pathway available under the BCPIA. *See* 42 U.S.C. § 262(k).

On August 3, 2018, Amgen served its Initial Disclosure of Asserted Claims and Infringement Contentions.

On February 7, 2019, Amgen served Amended Infringement Contentions.

On August 22, 2019, Plaintiff proposed its current motion seeking to file second amended infringement contentions. The proposed amendments are: **(1)** to narrow the disputed issues in the case by no longer asserting claims in U.S. Patent No. 8,952,138 (which was actually dismissed from the case on September 16, 2019) and reducing the number of asserted claims for U.S. Patent No. 9,856,287 (“the ‘287 patent”); **(2)** to “clarify and provide additional detail regarding Amgen’s infringement theories in light of the parties claim construction proposals . . . .”; and **(3)** to correct an inadvertent “cut-and-paste error” in the February 7 contentions.

On September 12, 2019, Defendants advised that they consent to the first proposed amendment; they oppose proposed amendments 2 and 3. Defendants contend that Amgen’s application lacks “good cause” as contemplated by the Local Patent Rules; is allegedly Amgen’s “latest effort to unfairly obtain litigation advantages by adopting new and (often contradictory) positions”; and should either be denied or, at a minimum, deferred until after claim construction has been heard by the Court.

Amgen counters that there is ample good cause for its proposed amendments,

including that no fact depositions have been taken; discovery is still open; and a claim construction hearing has not been scheduled yet, let alone decided. It further claims that the amendments would actually simplify claim construction and correct a ministerial error that occurred when revising prior versions of the contentions.

### **LEGAL STANDARD**

“The Local Patent Rules exist to further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their case.” *King Pharm., Inc. v. Sandoz*, 2010 WL 2015258, at \*4 (D.N.J. May 20, 2010). The Patent Rules “are designed to require the parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed.” *Celgene Corp. v. Natco Pharma Ltd.*, 2015 WL 4138982, at \*4 (D.N.J. July 9, 2015). Nevertheless, the Patent Rules are not “a straightjacket into which litigants are locked from the moment their contentions are served . . . [a] modest degree of flexibility exists, at least near the outset.” *Astrazeneca AB v. Dr. Reddy’s Labs, Inc.*, 2013 WL 1145359 (D.N.J. Mar. 18, 2013).

Local Patent Rule 3.7 governs requests to amend contentions. The Rule allows for amendments “only by order of the Court upon a timely application and showing of good cause.” *Id.* Good cause “considers first whether the moving party was diligent in amending its contentions and then whether the non-moving party would suffer prejudice if the motion to amend were granted.” *Astrazeneca*, 2013 WL 1145359, at \*3.

Rule 3.7 provides a “non-exhaustive” list of examples that may, absent undue prejudice to the adverse party, support a finding of good cause: “(a) a claim construction by the Court different from that proposed by the party seeking amendment; (b) recent discovery of material prior art despite earlier diligent searches; (c) recent discovery of nonpublic information about the Accused Instrumentality which was not discovered, despite diligent efforts, before the service of Infringement contentions; (d) disclosure of an infringement contention by a Hatch-Waxman Act party asserting infringement . . . that requires response by the adverse party because it was not previously presented or reasonably anticipated . . . .” *Id.* (emphasis added).

Courts have also considered the following in determining whether good cause exists: reason for the delay; importance of the information to be excluded; the danger of unfair prejudice; and the availability of a continuance and the potential impact of a delay on judicial proceedings. *See, e.g., Int’l Development, LLC v. Simon Nicholas Richmond and Adventive Ideas, LLC*, 2010 WL 3946714, at \*3 (D.N.J. Oct. 4, 2010).

In sum, amendment will be permitted when there is “(1) a timely application, (2) there is a showing of good cause, and (3) the adverse party does not suffer undue prejudice.” *Celgene Corp.*, 2015 WL 4138982, at \*4.

### **DECISION**

The Court is satisfied that Amgen has been diligent and shown good cause for its proposed amendments,<sup>1</sup> and that none of the amendments will cause undue prejudice to

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<sup>1</sup> As discussed on page 2, *supra*, proposed Amendment 1 is not opposed; what remains

Defendants.

**A. Good Cause**

With respect to Amendment 2, Amgen explains that based upon discovery received in the case and its review of the parties' claim construction submissions, it wishes to "provide a more detailed explanation" of infringing activity without adding any new infringing instrumentalities. The parties have sought to seal the specifics of this information and have redacted it from the Court's public docket. A motion to seal is currently being briefed. In short and generic language, Amgen's proposed Amendment 2 involves describing the relationship between "thiol-pair ratio" and "thiol-pair buffer strength" and a series of mathematical calculations – the end result being that Amgen claims that Amendment 2 shows that the relationships of the two are the same regardless of which of a series of disclosed equations are used.

The receipt and review of discovery and claim construction materials is sufficient good cause to allow an amendment of infringement contentions in a case positioned like this; that is, with discovery still open, with the proposed amendments appearing designed to simplify -- as opposed to expand and complicate -- claim construction, and in light of the acknowledgment that contentions should not be treated as final, early in the case and before much discovery has been exchanged.

With respect to Amendment 3, Amgen explains that, in preparation of its February 7, 2019, amended contentions, counsel made an "inadvertent cut-and-paste

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are proposed Amendments 2 and 3.

error” in the text of the contentions – specifically, that certain text regarding the ‘187 patent was copy and pasted into contentions relating to a claim in the ‘287 patent.

Defendants oppose this amendment on the basis that they find it “hard to accept” that Amgen did not sooner realize this mistake had occurred; that such a mistake is actually a large change to infringement positions; and that any attorney-error of the sort is not a basis under the Local Rules to amend contentions. The Court disagrees.

Rule 3.7 specifically states that it contains a “non-exhaustive” list of bases to allow amendment of contentions, and courts have acknowledged inadvertence and mistake as grounds to support amendment of contentions. *See, e.g., TFH Publ. Inc.*, 705 F. Supp. 2d at 366; *Int’l Dev., LLC*, 2010 U.S. Dist. LEXIS 106616 at \*3. Moreover, it would be a waste of judicial resources to push forward with claim construction as it has been submitted. It is impractical and unreasonable to ask the District Court, currently in a state of judicial emergency, to evaluate claim construction as is - knowing well that it contains what one side claims is an error - only to have a previously known and raised request to amend be immediately brought after time and resources are dedicated to construing the disputed claims.

**B. No Prejudice**

In deciding whether Amgen’s proposed amendments would prejudice Defendants, the Court considers whether the proposed amendments would: (1) require the opposing party to expend significant additional resources; or (2) significantly delay resolution of the dispute. *See, e.g., TFH Publications*, 705 F. Supp. 2d at 366.

There is no undue prejudice in this case for a number of reasons.

First, discovery is still open. Fact depositions have not commenced. Opening expert reports are not due for some time. A claim construction hearing has not been scheduled - and obviously claim construction has not been decided. Given the state of the Court's general docket and the fact that this District is in a judicial emergency, motions and a trial are far away.

Second, Defendants claim that any amendments would result in "significant prejudice" and require the expenditure of resources to respond to the amendments. While there could be some resulting prejudice, denial of leave to amend requires that additional work required be substantial or "undue." *See, e.g., AS Am., Inc. v. Masco Corp. of Ind.*, 2013 WL 4084237, at \*3 (D.N.J. Aug. 13, 2013) ("[a]lthough defendant's amendment may require some additional work on plaintiff's part, the additional work is not significant or vexatious."). Here, undue prejudice has not been shown. Amgen's amendments reduce the number of claims at issue in the case, and moreover, Amgen has stated that it would not oppose any defense application to amend non-infringement contentions based on the amendments allowed in this motion.

Third, no party identifies any additional discovery would be needed as a result of the proposed amendments.

Fourth, there is no pending motion or dispositive motion that would be impacted by the amendments. The amendment will not prolong the case.

For the above reasons, there is no undue prejudice to Defendants, and the

amendments will be allowed.

**CONCLUSION**

For the reasons stated above, Amgen's motion for leave to amend its infringement contentions is **GRANTED**.

**s/Mark Falk**  
**MARK FALK**  
**Chief U.S. Magistrate Judge**

**Dated: October 24, 2019**